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**SOLBEC  
PHARMACEUTICALS LTD**

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**UPDATE ON TGA MATTER**

Perth, Australia. 29 November 2006: The Company (ASX:SBP) refers to its announcement of 13 November 2006 in which it advised it had voluntarily suspended enrolments for its Phase II clinical trials pending further discussions with the Therapeutic Goods Administration ("TGA").

In the interest of shareholders and the market, and to enable the position to be properly understood the Directors provide the following comments:

1. The human clinical data from Solbec's Phase I/IIA trial completed at Sir Charles Gairdner Hospital is not in dispute or challenged. These trials determined Coramsine<sup>®</sup> was safe to use and well tolerated in patients with advanced cancer. Notwithstanding the fact that the primary end point of the trials was to test safety and tolerability of Coramsine<sup>®</sup> evidence of preliminary efficacy was also noted in three of the eight patients who completed six or more cycles of treatment.
2. Based on the data generated from the Phase I/IIA human clinical trials and the recommendation of the Phase I/IIA Principal Investigator Solbec proceeded with the Phase IIB trials to further test the efficacy of Coramsine<sup>®</sup>. Renal cell carcinoma and malignant melanoma were chosen as the first two cancer targets for these Phase II efficacy trials.
3. Coramsine's<sup>®</sup> Orphan Drug Status granted by the United States Food and Drug Administration remains in full force and authority.
4. The concerns of the TGA primarily relate to the details and extent of the toxicological data from animals in the preclinical work and the details and description of this in the Investigator's Brochure submitted to hospitals selected as potential trial sites for the impending Phase II trials.
5. Full details and results of Solbec's human data, particularly relating to safety and tolerability noted in the Phase I trial, have been provided to the TGA and no concern or questions have been raised in relation to this data.

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12/11/06

6. Solbec, along with its independent toxicologist and specialist regulatory advisers are preparing a development plan for submission to the TGA which it anticipates lodging within 3-4 weeks.

Whilst the issues raised by the TGA are of concern to Solbec, the Directors consider it important to provide these comments to enable the situation to be understood.

**Further information:**

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**Background Information**

**About Solbec**

Solbec Pharmaceuticals Ltd identifies naturally-occurring compounds with potential in the development of better therapies for debilitating conditions and life-threatening diseases. With the assistance of a \$2.26M Australian Government Commercial Ready grant the company is currently progressing its key project, Coramsine® for the treatment of advanced solid tumours. The two proprietary ingredients of Coramsine® were isolated from the fruit of the Devil's Apple (*Solanum linnaeanum*). They show activity against some cancers and cause potentially therapeutic changes to the immune system. In addition to human health, Coramsine® has potential application to animal health and diagnostics. Solbec's business strategy is to partner or out-license Coramsine® for the final stages of pre-commercial development and marketing.

[www.solbec.com.au](http://www.solbec.com.au)